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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,457

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Petra Cirpus

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23416 7590 10/27/2010  
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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT

PAPER NUMBER

1638

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,457	<b>Applicant(s)</b> CIRPUS ET AL.	
	<b>Examiner</b> Elizabeth F. McElwain	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35, 38-44 and 47-66 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 and 15-35, 38-44 and 47-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-14 and 64-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1638

### **DETAILED ACTION**

The amendment filed August 20, 2010 has been entered.

Claim 1 is newly amended.

Claims 64-66 are newly submitted.

Claims 36-37 and 45-46 are cancelled.

Claims 1-35, 38-44 and 47-66 are pending.

Claims 7-9, 15-35, 38-44 and 47-63 are withdrawn as drawn to non-elected inventions.

Claims 1-6, 10-14 and 64-66 are examined on the merits.

### ***Election/Restrictions***

This application contains claims 7-9, 15-35, 38-44 and 47-63 drawn to an invention nonelected with traverse in the reply filed on August 20, 2010. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. In addition, claim 6 recites non-elected SEQ ID numbers.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. It is noted that English translations of the foreign priority documents have not been provided.

### ***Claim Objections***

New claim 64 is objected to for the recitation of “with one double in”, which should read “with one double bond in”.

Art Unit: 1638

Claim 6 is objected to for reciting nonelected SEQ ID numbers: 53, 113, 54 and 114.

Amendment of the claims to delete the nonelected subject matter is requested, as stated in the last office action.

1. Applicants' arguments filed August 20, 2010 have been fully considered but they are not persuasive. Applicants argue that the nonelected SEQ ID numbers will be maintained so that they may be rejoined upon allowance of the generic claim.
2. The Examiner will maintain the objection pending determination of an allowable generic claim. At this time, the generic claim is not in condition for allowance.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1638

2. Claims 1-6, 10-14 and 64-66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 5-11 of copending Application No. 10/566,944. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 2 and 5-11 of Application No. 10/566,944 is drawn to a method of making fatty acids of formula I in an organism by transforming the organism with a delta-6 desaturase, a delta-6 elongase, a delta-5 desaturase, a delta-5 elongase and a delta-4 desaturase, which would be obvious in view of the present claim drawn to a method having the same steps, wherein the level of compounds of formula I would be inherent in seeds produced by the same method. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Applicants' arguments filed August 20, 2010 have been fully considered but they are not persuasive. Applicants state that they will "consider filing an appropriate terminal disclaimer upon an indication of allowable subject matter".

4. The rejection is maintained, given that no terminal disclaimer has been filed, nor has applicant argued the rejection. Applicants are advised that the claims will not be in condition for allowance without resolution of this issue.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1638

6. Claims 1-6, 10-14 and 64-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in an organism with at least 20% of these compounds based on total lipid content by introducing into the organism coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase that elongates only unsaturated C20-fatty acids, and a delta-4 desaturase. Claim 5 recites that the seed has at least 1% by weight of docosahexaenoic acid. Claim 64 requires that the delta-5 elongase activity elongates only unsaturated C20 fatty acids with one double bond in the delta-5 position. Claim 65 requires that 20% of the total lipid content of the seeds comprises fatty acids having 20 or 22 carbon atoms in the fatty acid chain. Claim 66 identifies numerous plant species.

7. The specification discloses OtElo1 (SEQ ID NO: 67), OtELO1.2 (SEQ ID NO: 113) and TpELO1 (SEQ ID NO: 43) that have the claimed delta-5 desaturase activity when expressed in yeast (see pages 111, 116 and 144). And the specification seems to disclose that an elongase from *Ostreococcus tauri* has the claimed activity when expressed in a plant (page 176, Example 61 and Figure 32). Though, it is unclear from the specification what sequences are present in the pSUN-8G construct that was transformed into Brassica plants. However, the specification also discloses about 20 other sequences that are identified as delta-5 elongase sequences that are isolated from about 10 other species. While the specification provides three examples of delta-5

Art Unit: 1638

desaturases that elongate only unsaturated C20-fatty acids, there are also 20 other examples of those that appear to have a broader specificity, and the specification does not set forth any distinguishing structural features that define the claimed functional genus.

The Federal Circuit has clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

“A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” In addition, “The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA’s relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention”. *See University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

Art Unit: 1638

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

8. Claims 1-6, 10-14 and 64-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for production of polyunsaturated C22 fatty acids by transforming a plant with the delta-5 elongase of SEQ ID NO: 67 that elongates only unsaturated C20 fatty acids in combination with genes encoding a delta-6 desaturase, a delta-6 elongase, a delta-desaturase and a delta-4 desaturase, does not reasonably provide enablement for the use of any delta-5 elongase that elongates only unsaturated C20 fatty acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claims are drawn to a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in an organism with at least 20% of these compounds based on total lipid content by introducing into the organism coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase that elongates only unsaturated C20-fatty acids, and a delta-4 desaturase. Claim 5 recites that the seed has at least 1% by weight of docosahexaenoic acid. However, the specification only discloses OtElo1 (SEQ ID NO: 67), OtELO1.2 (SEQ ID NO: 113) and TpELO1 (SEQ ID NO: 43) that have the claimed delta-5 desaturase activity when expressed in yeast (see pages 111, 116 and 144). And the specification seems to disclose that an elongase from *Ostreococcus tauri* has the claimed activity when expressed in a plant (page 176, Example 61 and Figure 32). Though, it is unclear



Art Unit: 1638

from the specification what sequences are present in the pSUN-8G construct that was transformed into Brassica plants.

9. However, the specification also discloses about 20 other sequences that are identified as delta-5 elongase sequences that are isolated from about 10 other species. While the specification provides three examples of delta-5 desaturases that elongate only unsaturated C20-fatty acids in yeast, there are also 20 other examples of those that appear to have a broader specificity, and the specification does not set forth any distinguishing structural features that define the claimed functional genus. And it appears that the specification only provides an example of one delta-5 elongase that elongates only unsaturated C20 fatty acids in plants. However, as stated above, it is unclear from the specification which sequences are present in the construct pSUN-8G.

10. Given the teachings in the specification of the large number of sequences that may be considered delta-5 elongases that do not have the claimed specific activity for elongation of only C20 fatty acids that are unsaturated, and given the lack of additional working examples of such sequences that function in a transformed plant, and given the absence of guidance with regard to identifying other sequences that have this specific activity, and in view of the breadth of the claims which are drawn to use of any sequence encoding a polypeptide having the claimed delta-5 elongase activity for transformation of any plant species for the production of a broad range of compounds that range from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds and the combined levels comprising at least 20% by weight of the lipid content, it would require undue experimentation by one skilled in the art to make and/or use the invention as broadly claimed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EFM

/Elizabeth F. McElwain/  
Primary Examiner, Art Unit 1638